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7. Author(s)
EPA, Office of Pesticide Programs, Registration Division

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US Environmental Protection Agency
Office of Pesticide Programs
Registration Division, TS-767C
401 M Street, S.W.
Washington, D.C. 20460

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This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

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EPA

Pesticide Fact Sheet

Name of Chemical: MONOCROTOPHOS
Reason for Issuance: REGISTRATION STANDARD
Date Issued: Sept. 30, 1985
Fact Sheet Number: 72

1. Description of Chemical

Generic Name: Dimethyl phosphate of 3-hydroxy-N-methyl-cis-crotonamide

Common Name: Monocrotophos

Trade Names: Azodrin; Apodrin; Bilobron; Crisodrin; Glore Phos 36; Hozodrin; Monocil 40; Monocron; Nuracron; Pillardrin; Plantdrin; Susrin; and Ulvair.

EPA Shaughnessy Code: 058901

Chemical Abstracts Service (CAS) Number: 6923-22-4

Year of Initial Registration: 1965

Pesticide Type: Insecticide/acaracide

Chemical Family: Organophosphate

U.S. and Foreign Producers: Shell Chemical Co. (U.S.A.)

2. Use Patterns and Formulations

Application Sites: Terrestrial, nondomestic food uses on cotton, peanuts and sugarcane. Terrestrial, nondomestic nonfood uses on tobacco, ornamental conifers (nursery stock), ornamental flowering plants (nursery stock), ornamental woody shrubs (nursery stock), and ornamental deciduous trees (nursery stock).

Types of Formulations: Soluble concentrate liquid

Types and Methods of Application: Aerial and ground application.

Application Rates: 0.125 - 1 pound per acre (lb/a)

Usual Carriers: CONFIDENTIAL BUSINESS INFORMATION

3. Science Findings

Summary Science Statement:

Toxicology, environmental fate, ecological effects, product chemistry and residue chemistry data gaps preclude the Agency from making a complete assessment for monocrotophos. However, based on available data, monocrotophos can be characterized as having very high acute oral toxicity to both humans and birds. Monocrotophos is a potent cholinesterase inhibitor (NOEL = 0.03 ppm in rats). Monocrotophos is also fetotoxic (NOEL = 1.0 ppm) but not teratogenic at the highest dose tested (2 mg/kg), decreases fertility at 9.0 ppm (NOEL = 2.7 ppm) and is weakly mutagenic in vitro.

Chemical Characteristics:

Technical monocrotophos is a reddish brown solid with a melting point of 25 to 30 °C. Its odor is characteristic of a mild ester. Monocrotophos is soluble in water, acetone, and alcohol. It is stable when stored in glass or polyethylene containers; stable in simple alcohols and glycols at room temperature; relatively stable in sunlight and nonvolatile at 100 °F; decomposes at 310 to 320 °F. At 20 °C, hydrolysis is quite slow. Its half-life in solution (2 parts per million (ppm)) at pH 7 and 38 °C is 23 days.

Toxicology Characteristics:

Current available toxicological studies on monocrotophos are as follows:

- Acute oral toxicity: rat, LD_{50} = 23 mg/kg (males) and 18 mg/kg (females), (Tox Category I).
- Acute dermal toxicity: rat, LD_{50} = 354 milligrams per kilogram (mg/kg) (Tox Category II).
- Primary eye irritation: rabbit, slight to moderate irritation and corneal opacity reversible by day 14 (Tox Category II).
- Primary Dermal irritation: rabbit, PIS = 0.6 to 1.0, slightly irritating (Tox Category IV).

Major routes of exposure: Application by ground and aerial equipment increases the potential for exposure of humans, livestock and wildlife due to spray drift. Human exposure to monocrotophos from handling, application and reentry operations is minimized by the use of approved respirators and other protective clothing.

Chronic toxicity results:

° Rat chronic feeding and oncogenicity:

Not carcinogenic at the highest dose tested (HDT) 9 ppm.
No Observable Effect Level (NOEL) - ChE I = 0.03 ppm.
Lowest Effect Level (LEL) - ChE I = 0.09 ppm.
Systemic NOEL = 0.9 ppm.
Systemic LEL = 9.0 ppm (body weight decrease in males; decreased survival in females). This study indicates that the rat is the most sensitive species for measuring cholinesterase inhibition (NOEL = 0.03 ppm) compared to the dog (NOEL = 1.6 ppm).

° Dog chronic feeding:

NOEL - ChE I = 1.6 ppm.
LEL - ChE I = 16.0 ppm.
Systemic NOEL = 16.0 ppm.
Systemic LEL = 100 ppm (salvation and tremors).

° Rat teratogenicity:

Fetotoxic effects were found at 2 mg/kg. The effects consisted of runting, reduced fetal weight and length (NOEL = 1.0 mg/kg), and maternal toxicity in the form of reduced body weight gain at 1.0 mg/kg (NOEL = 0.3 mg/kg). No teratogenic effect was observed at the HDT (2.0 mg/kg/day).

° Rat Reproduction:

Generated a reproductive (and offspring) NOEL of 2.7 ppm and an LEL of 9.0 ppm (as evidenced by decreased fertility, pup viability and weight, partly attributed to depressed maternal lactation).

° Mutagenicity:

A total of 19 studies evaluating monocrotophos for mutagenicity are available, but only 10 are adequate (acceptable). Monocrotophos is weakly mutagenic <u>in vitro</u>, as determined mainly from studies assessing DNA damage/repair and sister chromatid exchange.

Physiological and Biochemical Behavioral Characteristics

° Mechanism of Pesticidal Action:

Monocrotophos is a systemic and contact poison. As an organophosphate, monocrotophos exerts its toxic action by inhibiting certain important enzymes of the nervous system (cholinesterase).

° Metabolism and Persistence in Plants and Animals:

The metabolism of monocrotophos in animals and plants has not been adequately described. Metabolism studies utilizing ruminants and poultry will be required to fill the animal metabolism data gaps. Currently, no tolerances for residues of monocrotophos in animal products exist; however, monocrotophos and some of its metabolites have been identified in the milk, muscle, and liver of cows and in the milk of goats following ingestion of this chemical.

Additional plant metabolism data are required, including studies to reflect the potential for uptake of soil metabolites following foliar applications.

Environmental Characteristics

Monocrotophos hydrolyzes rapidly (half-life of 14-21 days at pH 9 and 25 ° C), with the rate decreasing at lower pH's and increasing at higher temperatures. Degradation on soil exposed to natural sunlight is rapid (half-life less than 7 days) and on dark control samples is slower (half-life approximately 30 days). Residues have a low potential for bioaccumulation in catfish and are depurated fairly rapidly.

Monocrotophos is mobil in soil and although it degrades rapidly, it may possess potential for groundwater contamination. Pertinent data (mobility, metabolism and dissipation) are necessary to fully assess monocrotophos's potential for ground water contamination.

Ecological Characteristics:

Avian Oral Acute Toxicity: Test results showed that acute oral toxicity for upland game birds ranges from 0.763 to 6.49 mg/kg; 1.58 to 4.76 mg/kg for waterfowl; 1.00 to 5.62 mg/kg for passerines and for the golden eagle, the value is 0.188 mg/kg (very highly toxic).

Avian Dietary Toxicity: Dietary studies on the ringed-neck pheasant and mallard duck resulted in dietary toxicity values of 3.1 and 9.6 ppm, respectively (very highly toxic).

Fish Acute Toxicity: Test results for warm water acute fish toxicity range from 12.1 ppm for bluegill sunfish to greater than 50 ppm for fathead minnows (moderately toxic).

Freshwater Invertebrate Acute Toxicity: Test results for acute toxicity to Daphnia magna were 0.034 ppm (very highly toxic).

Avian Reproduction: Test results are sufficient to characterize monocrotophos as not having an effect on the overall reproductive success of birds at levels of 0.1 to 3.0 ppm in the diet (non-toxic to reproduction). Typical reproductive effects in the field are unlikely from the use of monocrotophos. Rather more likely, breeding birds will be exposed to a toxic dose themselves or will lead/feed a toxic dose to their brood.

Honeybee Acute Toxicity: 0.350 micrograms per bee (highly toxic).

Monocrotophos is one of the most toxic pesticides to birds. Monitoring and incident reports contain numerous observations of avian mortality attributed to monocrotophos; thus, it has the potential for causing significant impacts on populations of avian wildlife. The field studies that have been submitted are inadequately designed and contain mostly cursory monitoring information; therefore, terrestrial field testing for effects on avian wildlife is needed. Monocrotophos has been reviewed under the cotton "cluster" for endangered species, and no jeopardy has been determined for endangered avian species. The Agency will initiate a formal consultation with the U.S. Fish and Wildlife Service Office of Endangered Species concerning potential adverse effects of monocrotophos on terrestrial species for the remaining uses.

Tolerance Assessment

Established tolerances for monocrotophos are published in 40 CFR 180.296 and 21 CFR 193.151 and are:

Commodity	Part per Million
potatoes	0.1
tomatoes	0.5
cottonseed	0.1
peanuts	.05
sugarcane	0.1
concentrated tomato products	2.0

The Agency is unable to complete a full tolerance assessment for the established tolerances because of residue chemistry data gaps including plant and animal metabolism studies and residue

data to determine whether food/feed additive tolerances must be proposed for the processed products of all the registered crops.

The NOEL for cholinesterase inhibition (ChE) has been set at 0.03 ppm (and for systemic effects at 0.9 ppm), generating an ADI of 0.00015 mg/kg/day (systemically, 0.0045 mg/kg/day), which results in the TMRC for previously published tolerances occupying 397 percent of the ADI (132% based on systemic effects). Thus, on either basis (ChE or systemic), the margin of safety has been exceeded for those tolerances already published which precludes granting any new requests.

The Agency requested, and the registrant agreed, to voluntarily delete the use of tomatoes from currently approved labels. The registrant has since submitted an application with revised labels removing both tomatoes and potatoes from their section 3 product labels. The elimination of the use of monocrotophos on tomatoes and potatoes lowers the TMRC to 66 percent of the ADI. Nevertheless, the Agency will not allow any new uses to be established for monocrotophos until the required residue chemistry data (including animal metabolism studies) have been submitted and evaluated so that a tolerance reassessment can be made.

4. Summary of Regulatory Position and Rationale

The Agency has determined that it should continue to allow the registration of monocrotophos. None of the criteria for unreasonable adverse effects listed in the regulations [§162.11 (a)] has been met or exceeded. However, because of gaps in the data base a full risk assessment cannot be completed.

The Agency will not allow any significant new uses to be established for monocrotophos until the residue chemistry data deficiencies have been satisfied, a tolerance reassessment is made, and a well-designed field test in birds has been evaluated.

Because of the high acute toxicity of monocrotophos to humans:

- All end-use products containing monocrotophos shall continue to be classified for restricted use.
- The Agency is requiring applicators with a high exposure to monocrotophos, mixers, and loaders to wear protective clothing. The use of backpack or knapsack sprayers for application of monocrotophos is being prohibited.
- The Agency will continue to require the reentry interval of 48 hours established under 40 CFR 170 for all outdoor uses of monocrotophos in order to minimize exposure to

workers entering treated areas, pending the receipt and evaluation of reentry data to assess the potential for exposure to workers coming in contact with monocrotophos.

Because of the high acute toxicity of monocrotophos to birds:

° The Agency is requiring a well-designed field test on birds. The field sites will include a number of sites in each growing area and will investigate monocrotophos exposure to birds from diet and drinking water and the effect on young fledglings using nest boxes. The design of the field testing protocols, selection of sensitive indicator species (including avian predators), and the selection of the test sites must be submitted to the Agency. This protocol must be approved by the Agency prior to the initiation of the study. Until the study is conducted and reviewed, label precautionary statements are required.

The Agency is requiring all end-use products registered for outdoor use to bear a restriction on rotating food or feed crops to monocrotophos treated soils unless monocrotophos is registered for use on the rotated crop. This restriction will remain in effect until such time as data are submitted and reviewed which allow the Agency to determine a time interval at which rotated crops planted in treated soil will be free of pesticide residues.

The Agency is not requiring additional residue data to determine if any detectable residues of the trimethyl phosphate (TMP) contaminant persists in raw agricultural commodities or processed foods unless the plant metabolism study being required shows that TMP persists.

5. Summary of Major Data Gaps

Product Chemistry: Data on product identity, ingredients, impurities, and physical and chemical characteristics.

Residue Chemistry: Studies on plant and animal metabolism, storage stability of samples, and residue data to determine whether food/feed additive tolerances are required for processed products of all registered crops.

Toxicology: Studies on acute and 21-day inhalation, dermal sensitization, general metabolism, and rabbit teratogenicity; and additional information on the mouse oncogenicity study.

Wildlife and Aquatic Organisms: A field test on birds and acute toxicity to estuarine and marine organisms.

Environmental Fate: Soil metabolism, mobility, dissipation and accumulation studies and data on reentry protection and spray drift.

6. Contact Person at EPA:

William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (TS-767)
Environmental Protection Agency
Washington, DC 20460
Tel. (703) 557-2600

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